Form SLICE-W: Worksheet for Designing Individual Field Trials Under SLICE® (Emamectin Benzoate) INAD 11-370

INSTRUCTIONS

1. Investigator must fill out Form SLICE-W for each trial conducted under this INAD **before** actual use of SLICE® (emamectin benzoate) medicated feed. The Investigator is responsible for accurate completion of Form SLICE-W.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form SLICE-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish parasite to be treated			
Fish species/stock to be treated			
Number of fish per rearing unit (i.e., tank, raceway, or pond)			
Number of rearing units to be treated		Number of untreated (i.e., control) rearing units	
Average number of fish per pound		Estimated total weight of treated fish (lbs)	
Intended SLICE® (emamectin benzoate) dosage		**50 ug per kg per day**	
Feed rate (% body weight to be fed per day)			
Planned duration of treatment (days)		**7**	
Estimated amount of medicated feed needed for proposed treatment (lbs or kg)			
Anticipated date treatment will be initiated			

STUDY DESIGN: Describe in detail the purpose of the clinical trial. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

☐ Investigator should initial here to indicate awareness that fish disposition must be in compliance with the FDA-mandated withdrawal time of 60 days as described in the Study Protocol.

USE AND DISPOSITION OF EMAMECTIN BENZOATE (SLICE®) MEDICATED FEED (Environmental Safety Considerations):

☐ Investigator should initial here to indicate awareness that SLICE® (emamectin benzoate) medicated feed usage and disposition must be in compliance with requirements described in the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Investigator should initial here to indicate that all personnel handling SLICE® (emamectin benzoate) medicated feed have read the Material Safety Data Sheet for SLICE® (emamectin benzoate) premix and have been provided personal protective equipment, in good working condition, as described in the Study Protocol.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

FORM SLICE-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form SLICE-1 **immediately** upon receipt of SLICE® (emamectin benzoate) premix or SLICE® (emamectin benzoate) medicated feed.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office.
4. **Note:** Both Investigator and Study Monitor should sign and date Form SLICE-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

Name of Drug	**SLICE® (Emamectin benzoate)**	INAD Number	**11-370**
Proposed Use of Drug	Treatment of external parasites that occur in a variety of freshwater fish species		
Date of CVM Authorization Letter	*To be Determined*		
Date of Drug Receipt		**Amount of Drug Received**	
Drug Lot Number		**Trial Number**	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study	**Yes**	Non-pivotal Study	---
Approximate Number of Treated Animals		**Approximate Number of Control Animals**	
Number of Animals Used Previously[1]			
Study Protocol Number	11-370		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	50 ug emamectin benzoate / kg fish / day for 7 days		
Methods(s) of Administration	Medicated-feed		
Withdrawal Period	60 days - all species		

[1] **To be filled out by the AADAP Office**

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____

Form SLICE-2a. Chemical Use Log for Clinical Field Trials Using SLICE® (emamectin benzoate) Medicated Feed Under INAD #11-370 - SLICE® Premix

Instructions:
1. Initiate Form 2a immediately upon receipt of SLICE® (emamectin benzoate) premix.
2. Each lot number of SLICE® (emamectin benzoate) premix may be used for multiple treatment regimes.
3. A signed copy of Form 2a should be sent to the Study Monitor at the end of the Study Year.
4. Original Form 2a should be archived at the investigating facility.

Quantity on Hand From Previous Page (lbs): _____ **Facility:** _____ **Reporting Individual:** _____

SLICE® Premix Lot Number	Date Received	Amount Received (g)	Date Used	Study Number	SLICE® Premix Used for Teatment (g)	SLICE® Premix Shipped[1] (g)	SLICE® Premix Disposal[2] (g)	SLICE® Premix On-hand (g)	Inventoried by (initials)

[1] Unused SLICE® Premix that is shipped to another facility participating in SLICE® INAD #11-370 (Note: SLICE® Premix can only be shipped to another facility with prior authorization by the AADAP Office).

[2] Unused SLICE® Premix that is disposed of by burial or in a landfill.

Investigator: _____
Signature and Date

Study Monitor: _____
Signature and Date

Form SLICE-2b. Chemical Use Log for Clinical Field Trials Using SLICE® (emamectin benzoate) Medicated Feed Under INAD #11-370 - SLICE® Medicated Feed

Instructions:
1. Initiate Form 2b immediately upon receipt of SLICE® (emamectin benzoate) medicated feed.
2. Each lot number of SLICE® (emamectin benzoate) medicated feed should be used for a single treatment regime.
3. A signed copy of Form 2b should be sent to the Study Monitor at the end of the study, or at the end of the Study Year.
4. Original Form 2b should be archived at the investigating facility.

Quantity on Hand From Previous Page (lbs): _____ **Facility:** _____ **Reporting Individual:** _____

SLICE® Medicataed Feed Lot Number	Date Received	Amount Received (lbs)	Dates Used	Study Number	SLICE® Medicataed Feed Used for Teatment (lbs)	SLICE® Medicataed Feed Shipped[1] (lbs)	SLICE® Medicataed Feed Disposal[2] (lbs)	SLICE® Medicataed Feed On-hand (lbs)	Inventoried by (initials)

[1] Unused SLICE® medicataed feed that is shipped to another facility participating in SLICE® INAD #11-370 (Note: SLICE® medicataed feed can only be shipped to another facility with prior authorization by the AADAP Office).

[2] Unused SLICE® medicataed feed that is disposed of by burial or in a landfill.

Investigator: _____ **Study Monitor:** _____

Signature and Date **Signature and Date**

Form SLICE-3: Results Report Form for Clinical Field Trials Using SLICE® (emamectin benzoate) Medicated Feed Under INAD 11-370

INSTRUCTIONS

1. Investigator must fill out Form SLICE-3 no later than 10 days after completion of treatment. Study Number must be recorded on all pages of Form SLICE-3. Attach lab reports and other information.
2. If SLICE® (emamectin benzoate) was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 4 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office for inclusion in the permanent file.
4. Note: Both Investigator and Study Monitor should sign and date Form SLICE-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

SLICE® (emamectin benzoate) lot number		Medicated feed manufacture/preparation date	
Treatment dosage	**50 ug/kg bw/day**	Treatment duration	**7 days**
Fish species treated		Fish parasite treated	
Number of rearing units treated		Number of fish per treated rearing unit	
ID of all treated rearing units (e.g. Tank 5, Pond 6B)			
Total number of fish treated			
Number of control units		Number of fish per control unit	
Number of fish per pound		Average fish length (in)	
Preparation of medicated feed (i.e. top-coated at your facility or prepared by feed manufacturer)			
Feed type (manufacturer, moist vs dry, particle size)			
Feed rate (% BW fed per day)			
Date treatment initiated		Date treatment completed	

Daily Mortality Record

INSTRUCTIONS

1. Investigator must fill out the Daily Mortality Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
3. Water temperature and individual tank mortality should be recorded on a daily basis.
4. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Pre-treatment Period	5									
	4									
	3									
	2									
	1									
Treatment Period	1									
	2									
	3									
	4									
	5									
	6									
	7									
Post-treatment Period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									

Daily Mortality Record (Supplemental Post-treatment Period Data)

INSTRUCTIONS

1. Investigator should fill out the Daily Mortality Record (Supplemental Post-treatment Period Data) **only** if data is collected for more than 10 days post-treatment.
2. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Post-treatment	11									
	12									
	13									
	14									
	15									
	16									
	17									
	18									
	19									
	20									
	21									
	22									
	23									
	24									
	25									
	26									
	27									
	28									

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)		Dissolved Oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - $CaCO_3$ (mg/L)	

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Describe general fish behavior, including feeding behavior. Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: ☐ pre-treatment ☐ post-treatment

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

OBSERVED WITHDRAWAL PERIOD:

Observed withdrawal period: ☐ **60 days**

Investigator should initial here to indicate compliance with established withdrawal period

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

DISPOSITION OF SLICE® (EMAMECTIN BENZOATE) MEDICATED FEED

☐ Use and disposition of all SLICE® (emamectin benzoate) medicated feed followed Study Protocol guidelines and has been clearly identified on Form SLICE-2b (Investigator should initial)

☐ **NEGATIVE REPORT:** SLICE® (emamectin benzoate) medicated feed was not used at this facility under this Study Number during the reporting period (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Form SLICE-3s: Supplemental Information Documenting Level of Parasite Infestation Pre-Treatment and Post-Treatment

INSTRUCTIONS

1. Investigator should fill-out one copy of Form SLICE-3s for each rearing unit treated.
2. Be sure to include STUDY NUMBER in upper left-hand corner of this form.
3. Data on Pre-treatment level of infestation should be collected within 5 days prior to the initiation of treatment.
4. Data on Post-treatment level of infestation should be collected at least once.
5. Note: Each sampling (i.e., pre- and post-treatment) should include data from a minimum of 10 fish, and completed Form SLICE-3s's should be appended to Form SLICE-3.

Rearing Unit ID: _____

Pre-treatment		
Date	Fish Number	Number of Parasites
	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	
	11	
	12	
	13	
	14	
	15	
	16	
	17	
	18	
	19	
	20	
	21	
	22	
	23	
	24	
	25	
	26	
	27	
	28	
	29	
	30	

Post-treatment[1]			
Date	Days Post-treatment	Fish Number	Number of Parasites
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	
		9	
		10	
		11	
		12	
		13	
		14	
		15	
		16	
		17	
		18	
		19	
		20	
		21	
		22	
		23	
		24	
		25	
		26	
		27	
		28	
		29	
		30	

[1] Additional copies of table for post-treatment infestation level are available on page 2 of this form

Additional Documentation of Level of Parasite Infestation Post-Treatment

☐ Note: If data on post-treatment level of parasite infestation is only collected once, please simply write "N/A" in the box

Rearing Unit ID: _____

Post-treatment			
Date	Days Post-treatment	Fish Number	Number of Parasites
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	
		9	
		10	
		11	
		12	
		13	
		14	
		15	
		16	
		17	
		18	
		19	
		20	
		21	
		22	
		23	
		24	
		25	
		26	
		27	
		28	
		29	
		30	

Post-treatment			
Date	Days Post-treatment	Fish Number	Number of Parasites
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	
		9	
		10	
		11	
		12	
		13	
		14	
		15	
		16	
		17	
		18	
		19	
		20	
		21	
		22	
		23	
		24	
		25	
		26	
		27	
		28	
		29	
		30	